UNITED STATES PATENT APPLICATION

COMPOSITE BONE MATERIAL IMPLANT AND PROSTHESIS

This is a Patent Application filed for the invention by Thomas L. Meredith, of a "Composite Bone Material Implant and Prosthesis."

Field of the Invention

This invention generally relates to the field of bone composite implants and a method of forming bone composites. The composite is generally formed from a process comprising grinding bone tissue to form ground tissue, molding the ground bone tissue into a bone composite, and optionally applying a binder to the bone composite.

One object of the current invention is to provide a composite material utilizing bone powder and/or fragments as well as a method to manufacture and shape the composite into usable implants and/or bone prostheses.

Background of the Invention

The practice of donating and transplanting bone tissue is beginning to form an important part of therapy for a number of ailments involving bone.

Tissue grafting of living tissue from the same patient, including bone grafting, is well known in medical science. Tissue such as bone is removed from one part of a body (the donor site) and inserted into tissue in another (the host site) part of the same (or another) body. With respect to living bone tissue, it has been desirable in the past to be able to remove a piece of living tissue graft material which is the exact size and shape needed for the host site where it will be implanted, but it has often proved very difficult to achieve this goal.

Until recently, developers of bone transplants and prostheses have believed that it is desirable to maintain graft tissue in a living state during the grafting process. There is no doubt that the use of living tissue in a graft will promote bone healing, but recent surgical experience has shown that healing can be achieved with allografts of non-living bone material which has been processed.

Processing of bone material which does not contain living tissue is becoming more and more important. Non-living bone grafting techniques have been attempted both for autografts and for allografts. For example, Nashef U.S. Patent No. 4,678,470 discloses a method of creating bone graft material by machining a block of bone to a particular shape or by pulverizing and milling it. The graft material is then tanned with glutaraldehyde to sterilize it. This process can produce bone plugs of a desired shape.

In the Nashef process, the process of pulverizing or milling the bone material destroys the structure of the bone tissue. The step of tanning it with glutaraldehyde then renders the graft material completely sterile.

It is now possible to obtain allograft bone which has been processed to remove all living material which could present a tissue rejection problem or an infection problem. Such processed material retains much of the mineral quality of the original living bone, rendering it more osteoinductive. Moreover, it can be shaped according to known and new methods to attain enhanced structural behavior. In fact spine surgeons express a distinct preference for such materials, and at least one supplier, the Musculoskeletal Transplant Foundation (MTF), has introduced femoral ring allografts for spine surgeries.

Research shows that such allografts are very favorable for spinal surgery. According to Brantigan, J.W., Cunningham, B.W., Warden, K., McAfee, P.C.,

and Steffee, A.D., A compression Strength of Donor Bone for Posterior Lumbar Interbody Fusion, Spine, Vol. 18, No. 9, pp.12113-21 (July 1993):

> Many authors have viewed donor bone as the equivalent of autologous bone. Nasca, et al. . . . compared spinal fusions in 62 patients with autologous bone and 90 patients with cryopreserved bone and found successful arthrodesis in 87% of autologous and 86.6% of allograft patients. (Citations omitted.).

A drawback of fabricating transplants and prostheses from donated allograft is that the process necessitates discard of a great deal of scrap and powdered bone material. Good quality donated bone is a scarce resource, so that devising a method of using scrap and powdered allograft bone material would be of great assistance to this highly beneficial endeavor. The present invention uses powdered bone to make solid shapes. The results of the present invention are superior to the prior art processes and the process and composite of the present invention allows for a greater amount of donor bone to become available. For example, with the present invention, bone can now be used from older donors. With a transplanted allograft, older bone may be too brittle and weak.

In the fabrication of bone transplants, it was observed that bone material which yields to compressive loads at the exterior surfaces without significant

degradation of the interior structural properties, such as cancellous or trabecular bone, can be shaped. It is not unusual that reshaping of a graft tissue is necessary to obtain the best possible graft. In particular, bone tissue may be stronger and better able to bear force when it is denser and more compact.

Additionally, prior art techniques have a serious limitation in that bone parts and bone products made from allograft cortical tissue may be limited in size, dimension and shape because of the anatomical limits on the thickness and length of the source bone. With the method of the present invention, many shapes and forms can be fabricated from allograft cortical bone tissue including pins, screws, plates, intervertebral discs, and the like for use in surgery.

Allograft bone occurs in two basic forms: cancellous bone (also referred to as trabecular bone) and cortical bone. Cortical bone is highly dense and has a compound structure comprised of calcium hydroxyapatite reinforced with collagen fiber. In the present invention, cortical bone tissue is preferred.

Compression of allograft bone is desirable from general considerations. Generally, bone samples are stronger when they are more dense. Compressing allograft bone increases its density and thus generally strengthens the allograft. In addition, recent studies have indicated that the shell of vertebral

bone is very much like condensed trabecular bone. Mosekilde, L., A Vertebral structure and strength in vivo and in vitro, Calc. Tissue Int. 1993;53 (Suppl) :121-6; Silva, M.J., Wang, C., Keaveny, T.M., and Hayes, W.C., A Direct and computed tomography thickness measurements of the human lumbar vertebral shell and endplate, Bone 1994:15:409-14; Vesterby, A., Mosekilde, L., Gunderson, H. J.G., et al., Biologically meaningful determinants of the in vitro strength of lumbar vertebrae, Bone 1991;12:219-24.

Compression also allows conversion of larger irregular shapes into the desirable smaller shape, thereby permitting more disparate sources of allograft bone to be used. By compressing bone to a given shape it is possible to configure the allograft to match a preformed donee site prepared by using a shaped cutter to cut a precisely matching cut space. In particular, this method of formation facilitates the formation of match mated surfaces of the implant for the formation of a particular shape for skeletal repair or revision.

For the reasons stated above, in certain embodiments of the present invention, compression is useful as part of the molding step in forming the bone composites of the present invention.

It is known that allograft bone can be reshaped into one of many configurations for use as an implant. Various methods, including that of

Bonutti, U.S. Patents Nos. 5,662,710 and 5,545,222, can be used to shape allograft material into the desired shape.

A goal of a bone composite transplant is that the transplant is readily received and hosted by the receiving mammal, with bone fusion occuring (i.e., the composite should be biocompatible and osteoinductive). Today, the only other osteoinductive implants are allograft shapes that have been cut and shaped from cadaver donated bone. This method has serious drawbacks in that it is difficult for sufficient fusion to take place and the implant usually lacks sufficient structural strength and density.

U.S. Patent No. 6,025,538 to Yaccarino, III, discloses allograft bone devices for surgical implantation in the bone tissue.

U.S. Patent No. 5,439,864 to Pruitt, et al., discloses shaped demineralized bone for use in the surgical repair of bone defects.

U.S. Patent No. 5,662,710 to Bonutti, discloses a tissue press for shaping or compressing a piece of graft tissue.

In response to the need for a composite material to make use of bone fragments and bone powder for fabricating implants and prosthetic devices for bone the current inventor developed the present invention.

Summary of the Invention

It is an object of the present invention to provide a bone composite that is readily received and hosted when received by another mammal. When successful, bone fusion occurs, and the biocompatible and osteoinductive process allows the body to lay down native bone in combination with the implanted bone composite.

The present invention relates to a method of forming a bone composite, comprising: providing bone tissue; grinding said bone tissue to form ground tissue; molding the ground bone tissue into a bone composite; optionally applying a binder to the bone composite; and optionally milling or refining the bone composite to the desired shape. Preferably, the bone tissue is substantially cortical bone tissue (i.e., greater than about 40-50%), and preferably, the bone tissue is substantially demineralized.

More preferably, the bone tissue is greater than about 50% cortical bone tissue, more preferably in the range of greater than about 50-70% cortical bone tissue, more preferably in the range of greater than about 50-90% cortical bone tissue, more preferably in the range of greater than about 50-95% cortical bone tissue, more preferably 90% cortical bone tissue, and more preferably greater than about 95% cortical bone tissue. The size of the ground bone particles can vary, but typically the particles will range in size from 125 to 850 microns in size.

The above-mentioned occurs at from 14.7 psi to about 30,000 psi.

The binder may be a cyanoacrylate and/or fibrin and is applied to the bone composite either before or after the molding step, preferably by injection, spray, or bath methods.

The present invention also encompasses bone tissue composites made therefrom. The composites may be, for example, a bone pin, screw, or prosthesis.

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Detailed Description of the Preferred Embodiments

The method and composite of the present invention can be used with any mammal, preferably horses and humans, most preferably humans. However, it is preferred that donor bone is the same species as recipient bone. That is, preferably human bone is used in making a bone composite that will be used by a human. Preferably the bone tissue is demineralized.

As stated above, preferably cortical bone tissue is used to form the composites of the present invention. More preferably, the composites are substantially cortical bone tissue, preferably above 50% cortical bone tissue, more preferably the bone tissue is greater than about 70%, 90%, or greater than about 95% cortical bone tissue.

Bone powder is placed in a mold and compressed using compression tooling. Then a form of adhesive is applied to the bone powder and permitted

to set. The composite bone blank, implant, or prosthesis is then removed from the mold and processed by machining and/or other surface preparation.

The type of mammalian bone that is most plentiful and most preferred as a resource for the composites of the present invention is cortical bone, which is also the form of bone tissue with the greatest compressive strength. Pulverized bone can be collected and separated into a number of batches, each batch comprising a different mean particle size. The particle size can vary from fine to coarse. The properties of the composite to be produced can be tailored by choice of particle size. For example, particles in the range of from about 125 to about 850 microns can be used for making bone composites useful for skeletal repair and revision.

In addition, pressure during formation can be tailored to the desired outcome. The pressure used in embodiments of the present invention can range from 14.7 to 30,000 psi. Lower pressures (i.e., from atmospheric to 15,000 psi) can be used to form bone composites useful for skeletal repair and revision. Higher pressures (i.e., from about 15,000 psi to about 30,000 psi) can be used to form bone composites useful for applications such as a bone screw.

The binder, when present, is added in an amount to sufficiently provides a cohesive ground bone composite that can be used in skeletal repair and

revisions methods without the ground bone coming apart. Preferably, the binder is present in an amount from .025mL to 10.0mL weight/volume. More preferably, the binder is present in an amount of from about 5% to about 50% of volume. Additionally, the particular binder used can be varied according to desired properties. For example, cyanoacrylates can be used as a binder in the production of cortical onlay plates and is preferably present in amount of from 20% to 30%. A binder may also be combined with at least one other binder. The binder is applied by injection, spray, bath, soaking or layering.

The above general ranges allow one of ordinary skill in the art to create a composite of proper density and mechanical properties and further allows the same basic device to be tailored to individual patients and situations.

As stated above, the preferred binder is a biocompatible cyanoacrylate. Preferred biocompatible cyanoacrylates include ester chain, N-butyl, and butyl cyanoacrylates.

In addition to cyanoacrylates, at least one other adhesive substance can optionally be used as a matrix to form composite bone material (in combination with or without at least one cyanoacrylate). For example, fibrin is a substance formed by human blood when it clots. Fibrin bonds the platelets together in the formation of, e.g., clots and scabs. Alternatively, fibrin glue can be manufactured. Other biocompatible adhesives can also be used. In addition,

there exist a number of biocompatible gels which can be used as a matrix adhesive for holding bone powder together to form a composite.

The following examples are intended to be for illustrative purposes and do not limit the spirit and scope of the present invention.

Example 1

This example discusses a process of the present invention for making a bone composite disc at atmospheric pressure. Pre-ground cortical bone is sieved to a range of from 125-850 microns. Sieved bone is then measured to a volume of 75% of desired disc size (volume). A polyethylene mold cored in the shape of ½ inch diameter by ¼ inch cylinder is then filled with 75% sieved bone, or .0368 cu/in. There is a polyethylene sized ½ inch by 1 inch plug at the base of the cored mold cylinder shape. This is used to eject cured bone disc. The bone particles are then slightly hydrated with a sterile water spray at greater than 1%. Cyanoacrylate measured at 25% of ½ inch by ¼ inch core volume, or 0.0123 cu/in is then poured into ground bone volume and allowed to wick for three minutes. The newly formed bone disc is then allowed to cure for a period of one hour at 14.7 p.s.i. After one hour, the mold ejection pin is pushed manually upward from base of mold, allowing the hard-set bone disc to be removed. Bone disc is then inspected for any out of tolerance measurement as well as shape. If trim is necessary, it may take place at this time.

Example 2

This example discusses a process of the present invention for making a bone composite screw with external high pressure. A specially designed high-pressure vessel is used. The design is two die plates which have been modeled in the shape of a ¼ inch diameter by 1 inch long screw. Each plate is half of one screw. Plates are made of high carbon stainless steel and through hardened. Multiple high tensile socket head cap screws are also used to hold die plates in place. A pneumatic over water high-pressure intensifier (pump) with the ability to generate 250,000 pounds of force is used. This pump is machined with ¼ inch high-pressure ports that are adaptable with high pressure fittings and tubing. Pre-ground cortical bone is sieved to a range of 125-180 microns. Sieved bone is then measured to a volume of 200% desired screw size and placed into a pressure vessel. The pressure vessel with ground bone is then placed into a special high-pressure polycarbonate (explosion proof) safety box and pressure is then applied. Pneumatic pressure is slowly regulated upward until a water gauge pressure of 15,000 p.s.i. is reached at cylinder squeeze side of the pressure vessel. Pressure is held for a period of one hour resulting with a force of 124,500 pounds at the bone screw. This amount of force is the result of 15,000 p.s.i. being subjected to the face of 3 ¼ bore cylinder diameter (where pressure x area = force). Actual bone screw density will increase with original bone volume squeezing from 200% down to

75%, which is near actual size of finished bone screw (greater than 5%). Pressure is released from pressure vessel and socket head cap screws are backed out. At this time, the bone screw may be manually removed from the die. The bone screw is hydrated with a light water spray and sterile water is allowed to wick into the bone screw for a period of three minutes. Gently, the bone screw may be bathed (dipped) into a cyanoacrylate pool and allowed to wick cyanoacrylate for about 10 seconds. The bone screw is then allowed to cure for a period of one hour, after which it may inspected for density, outside envelope dimensions and shape. The bone screw may now be implanted for skeletal repair and/or revision.

All patents, journal articles, and other publications cited in this disclosure are hereby expressly incorporated by reference.

From the foregoing description of the present invention, those skilled in the art will perceive improvements, changes and modifications, and understand that the specific details shown herein are merely illustrative. Such changes, modifications, and improvements do not depart from the spirit and scope of the following claims.